Claims

1. Use of pregelatinized starch in a hydrophilic controlled release formulation comprising one or more active ingredients and one or more viscous hydrophilic polymers to counter the impairing effect of ionic strength of the release medium on the controlled release of active ingredient(s) from said formulation.

2. Use of pregelatinized starch in a hydrophilic controlled release formulation comprising one or more active ingredients and one or more viscous hydrophilic polymers to maintain a controlled release of active ingredient(s) from said formulation in release media with changing ionic strength.

3. Use of pregelatinized starch according to claim 1 or 2 wherein the ionic strength of the release medium ranges up to 0.4.

4. Use of pregelatinized starch according to claim 1 or 2 wherein the ionic strength of the release medium is that encountered along the entire gastro-intestinal tract both in fasted as well as in fed conditions.

5. Use of pregelatinized starch according to claim 1 or 2 wherein the ionic strength of the release medium ranges from about 0.01 to about 0.2.

6. Use of pregelatinized starch in a hydrophilic controlled release formulation comprising one or more active ingredients and one or more viscous hydrophilic polymers to prevent dose-dumping from said formulation along the gastro-intestinal tract both in fasted as well as in fed conditions.

7. Use of pregelatinized starch according to claim 1, 2 or 6 wherein the hydrohilic controlled release formulation further comprises pharmaceutically acceptable formulating agents.

8. A hydrophilic controlled release formulation comprising pregelatinized starch, one or more active ingredients, one or more viscous hydrophilic polymers and optionally pharmaceutically acceptable formulating agents characterized in that the pregelatinized starch enables the formulation to maintain a controlled release of the incorporated active ingredient(s) in release media with changing ionic strength.

9. A formulation according to claim 8 wherein the pregelatinized starch enables the formulation to maintain a controlled release of the incorporated active ingredient(s) along the entire gastro-intestinal tract both in fasted as well as in fed conditions.

10. A hydrophilic controlled release formulation comprising pregelatinized starch, one or more active ingredients, one or more viscous hydrophilic polymers and optionally pharmaceutically acceptable formulating agents characterized in that the pregelatinized starch prevents dose-dumping from said formulation along the gastro-intestinal tract both in fasted as well as in fed conditions.

11. A formulation according to claim 8, 9 or 10 having the following composition:

Active ingredient(s)	0.01-50% (w/w)
Viscous hydrophilic polymer(s)	0.01-80% (w/w)
Pregelatinized starch	0.01-<80% (w/w)
Pharmaceutically acceptable formulating agents	ad 100% (w/w).

12. A formulation according to claim 11 wherein the viscous hydrophilic polymer comprises hydroxypropyl cellulose.

13. A formulation according to claim 8, 9 or 10 further comprising a water soluble polymer as dissolution-rate enhancer.

14. A formulation according to claim 13 wherein the water soluble polymer is hydroxypropyl β-cyclodextrin.

15. A formulation according to claim 8, 9 or 10 for use as a medicine.

16. Use of a formulation according to claim 8, 9 or 10 for the manufacture of a dosage form.

17. A dosage form comprising a therapeutically effective amount of a formulation according to claim 8, 9 or 10.

18. A dosage form according to claim 17 shaped as an optionally coated tablet.

19. A process for preparing a formulation according to claim 8, 9, 10 or 13, characterized by :

(a) optionally intimately mixing one or more active ingredients and a water soluble polymer;

(b) mixing one or more active ingredients or, if (a) was performed, mixing the intimate mixture prepared under (a) with pregelatinized starch, one or more viscous hydrophilic polymers and optionally some or all of the pharmaceutically acceptable formulating agents;

(c) compacting the powder mixture prepared under (b) by running it through a compactor, thus yielding plates;

(d) breaking the resulting plates down, thus yielding granules;

(e) optionally mixing the resulting granules with all or the remainder of the pharmaceutically acceptable formulating agents until homogeneous.